

Abstract

Method and device to detect therapeutic protein immunogenicity

The present invention consists of a time-temperature indicator device that has at least one parameter set to warn when a therapeutic protein drug has had a thermal history associated with increased risk of unwanted immunological activity. The indicator device is designed to remain with the drug as the drug travels throughout different links of the cold chain. In a preferred embodiment, the indicator device remains associated with the therapeutic protein from the time of manufacture up until the final few minutes before the drug is used. In alternate forms of the invention, additional parameters, including motion, light, and turbidity may also be monitored. Novel methods for determining therapeutic protein time-temperature immunological risk parameters, and programming or adjusting the indicator device, are also disclosed.